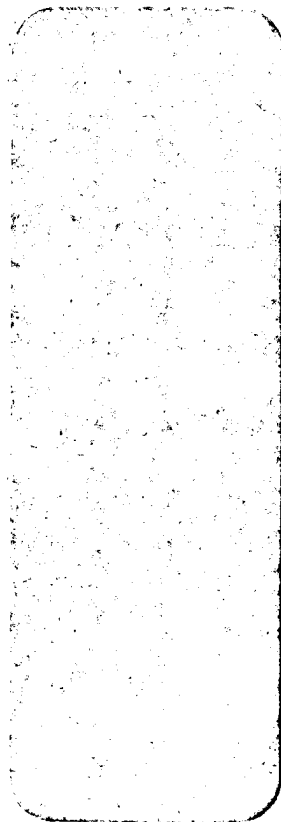
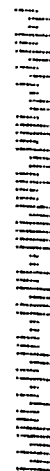


**AN EQUAL OPPORTUNITY EMPLOYER**

OFFICIAL BUSINESS  
PENALTY FOR PRIVATE USE, \$300

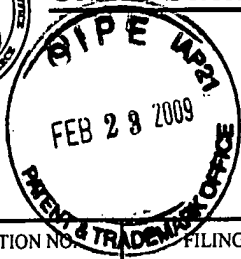


**RECEIVED**  
FEB 23 2009  
USPTO MAIL CENTER





# UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,045	04/25/2007	Zhi-Jie Ni	PP020540.0003	9706

27476 7590 02/19/2009  
NOVARTIS VACCINES AND DIAGNOSTICS INC.  
INTELLECTUAL PROPERTY R338  
P.O. BOX 8097  
Emeryville, CA 94662-8097

EXAMINER	
LOEWE, SUN JAE Y	

ART UNIT	PAPER NUMBER
1626	

MAIL DATE	DELIVERY MODE
02/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/576,045	NI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	SUN JAE Y. LOEWE	1626	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-104 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 60,65,84,87 and 90 is/are rejected.
- 7) ☒ Claim(s) 66,85,86,88 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1626

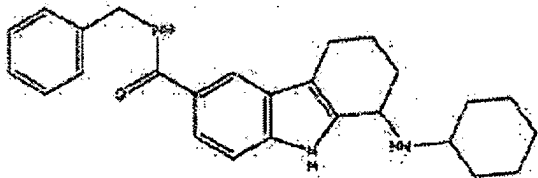
### DETAILED ACTION

1. Claims 1-104 are pending in the instant application.

#### *Election/Restrictions*

2. Applicant's election with traverse of Group II and species of Example 5 (structure below) is acknowledged. The traversal is on the ground that there is no burden in examining Groups I and II jointly. The argument has been considered, however, it is not found to be persuasive. The instant application is a national stage entry of PCT/US04/34169 therefore burden is not a consideration in determining the propriety of a restriction requirement.

The restriction requirement between groups I and II is still deemed to be proper and is hereby made FINAL.



3. Pursuant MPEP 1893.03

#### *“(Excerpts)”*

Once the national stage application has been taken up by the examiner, prosecution proceeds in the same manner as for a domestic application with the exceptions that:

(A) the international filing date >(or, if appropriate, the priority date)< is the date to keep in mind when searching the prior art; and

(B) unity of invention proceeds as under 37 CFR 1.475.

.....

¶ 18.20 National Stage Election of Species in 35 U.S.C.

Art Unit: 1626

*371 Applications*

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

[1]

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a). ”

the search and examination detailed in this office action was performed following the guidelines provided by MPEP 803.02

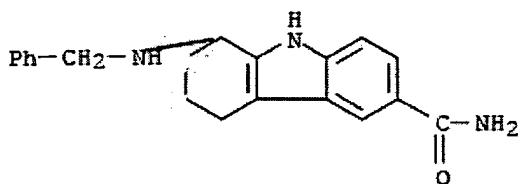
*“(Excerpts)”*

Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable \*\*, the provisional election will be given effect and examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration.”

Art Unit: 1626

The elected species appeared allowable. However, the non-elected species of



is obvious over the prior art. Thus, the provisional election was given effect and non-elected species were withdrawn from further consideration.

4. Claims 1-59, 61-64, 67-83, 89 and 91-104 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter. Applicant timely traversed the election of species requirement in the response dated November 25, 2008.

#### *Claim Objections*

5. Claims 60, 65, 66, 84-88 and 90 objected to for containing non-elected subject matter. The non-elected subject matter consists of compounds of Formula I/II that are not the elected species. Applicant will be entitled to rejoinder of non-elected species upon allowability of the generic claims.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

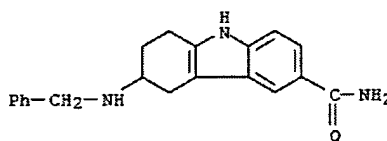
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1626

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 60, 65, 84, 87 and 90 rejected under 35 U.S.C. 103(a) as being obvious over King et al. (caplus an 1993:212888).

Determination of the scope and contents of prior art.



The reference teaches the compound

Ascertaining the differences between prior art and instant claims.

The prior art compound is a positional isomer of the non-elected species shown above, Section 3.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.

Position isomers are generally of sufficiently close structural similarity that there is a presumed expectation that such compound possess similar properties. MPEP §2144.09.

One of ordinary skill would be motivated to make the modification required to arrive at the instant invention with reasonable expectation of obtaining an additional compound for the same utility.

Thus, the instantly elected species is *prima facie* obvious over the prior art.

*Conclusion*

7. No claims allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sun Jae Y. Loewe whose telephone number is (571) 272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe/  
2-11-2009

/Golam M. M. Shameem/  
Primary Examiner, Art Unit 1626



<b>Notice of References Cited</b>	Application/Control No. 10/576,045	Applicant(s)/Patent Under Reexamination NI ET AL.	
	Examiner SUN JAE Y. LOEWE	Art Unit 1626	Page 1 of 1

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	King et al., caplus an 1993:212888
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

L18 ANSWER 198 OF 199 CAPLUS COPYRIGHT 2009 ACS on STN

AN 1993:212888 CAPLUS

DN 118:212888

OREF 118:36691a,36694a

TI Preparation and use of tetrahydrocarbazole derivatives as 5HT1 receptor agonists

IN King, Francis David; Gaster, Laramie Mary; Kaumann, Alberto Julio; Young, Rodney Christopher

PA Smithkline Beecham PLC, UK

SO PCT Int. Appl., 47 pp.

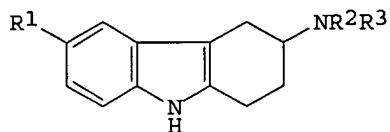
CODEN: PIXXD2

DT Patent

LA English

FAN.CNT 2

	PATENT NO.	KIND	DATE	APPLICATION NO.	DATE
	-----	---	-----	-----	-----
PI	WO 9300086	A1	19930107	WO 1992-GB1082	19920617
	W: AT, AU, BB, BG, BR, CA, CH, CS, DE, DK, ES, FI, GB, HU, JP, KP, KR, LK, LU, MG, MW, NL, NO, PL, RO, RU, SD, SE, US				
	RW: AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LU, MC, NL, SE, BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG				
	CA 2113726	A1	19930107	CA 1992-2113726	19920617
	CA 2113726	C	20080219		
	AU 9219775	A	19930125	AU 1992-19775	19920617
	AU 652842	B2	19940908		
	EP 591280	A1	19940413	EP 1992-912379	19920617
	EP 591280	B1	19980909		
	R: AT, BE, CH, DE, DK, FR, GB, IT, LI, LU, MC, NL, SE				
	JP 06508827	T	19941006	JP 1992-511086	19920617
	JP 3261502	B2	20020304		
	BR 9206237	A	19950411	BR 1992-6237	19920617
	HU 68961	A2	19950828	HU 1993-3731	19920617
	HU 218907	B	20001228		
	PL 169392	B1	19960731	PL 1992-301883	19920617
	PL 169410	B1	19960731	PL 1992-307118	19920617
	PL 171034	B1	19970228	PL 1992-311304	19920617
	CZ 282083	B6	19970514	CZ 1993-2861	19920617
	CZ 282061	B6	19970514	CZ 1996-1505	19920617
	CZ 282327	B6	19970611	CZ 1996-1506	19920617
	AT 170746	T	19980915	AT 1992-912379	19920617
	RU 2137474	C1	19990920	RU 1993-58534	19920617
	SK 280905	B6	20000912	SK 1993-1319	19920617
	SK 280906	B6	20000912	SK 1998-1054	19920617
	SK 280907	B6	20000912	SK 1998-1685	19920617
	ZA 9204658	A	19931224	ZA 1992-4658	19920624
	CN 1069726	A	19930310	CN 1992-108831	19920625
	CN 1034072	C	19970219		
	IL 102322	A	19970930	IL 1992-102322	19920625
	IL 117104	A	19970930	IL 1996-117104	19920625
	IL 117105	A	19980104	IL 1992-117105	19920625
	NO 9304800	A	19931223	NO 1993-4800	19931223
	US 5464864	A	19951107	US 1993-167846	19931223
	FI 103967	B1	19991029	FI 1993-5842	19931223
	HK 1014669	A1	20000714	HK 1998-116054	19981228
PRAI	GB 1991-13802	A	19910626		
	WO 1992-GB1082	W	19920617		
	IL 1992-102322	A3	19920625		
	US 1993-167846	A	19931223		
OS	MARPAT 118:212888				
GI					



I

AB Title compds. [I; R1 = H, halo, CF3, NO2, OH, alkyl, alkoxy, aralkoxy, CO2R4, (CH2)nCN, (CH2)nCONR5R6, (CH2)nSO2NR5R6, etc.; R4 = H, alkyl, aralkyl; R5, R6 = H, alkyl; R5R6N = heterocyclyl; n = 0-2; R2, R3 = H, alkyl, PhCH2; R2R3N = pyrrolidino, piperidino, hexahydroazepino] were prepared. Thus, 4-NCC6H4NHNH2.HCl and 4-phthalimidocyclohexanone (prepare given) were refluxed with NaOAc in HOAc to give 3-phthalimido-6-cyano-1,2,3,4-tetrahydrocarbazole. This was deprotected with N2H4 in EtOH to give 3-amino-6-cyano-1,2,3,4-tetrahydrocarbazole. In a 5-HT1-like receptor screen using dog saphenous vein, I had EC50 of 0.1-15  $\mu$ m. I are useful for treatment of headache, including migraine.

RN 147422-03-5 CAPLUS

CN 1H-Carbazole-6-carboxamide, 2,3,4,9-tetrahydro-3-[(phenylmethyl)amino]-, ethanedioate (1:1) (CA INDEX NAME)

CM 1

CRN . 147009-13-0

CMF C20 H21 N3 O

